DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
M2A60n

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

March 17, 1999

Ref: 99-DAL-WL-13

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. George M. Bethurum, President
Bethurum Research and Development
502 North 6th Street
Texas City, Texas 77590

Dear Mr. Bethurum:

This letter follows inspections of your firm conducted on September 15, 23, 24, November 23 and 30, 1998, and January 29, 1999, by investigators of the Food and Drug Administration and is in reference to the manufacture, promotion, marketing, and distribution of products by your firm.

Labeling for your products make the following claims:

> **"INTER-FEAR-ON-MAGIC"**.... "will eliminate all signs of cold sores or fever blister eruptions within two or three days when used as directed.";
>
> **"ISO-CEPTIC"**...."will eliminate all signs of bed sores when used at the first sign of an eruption within 4 to 5 days when used as directed.";
>
> **"EASY-IVY"**...."will eliminate all signs of contact with poison oak, ivy, or sumac within two or three days when used as directed.";
>
> **"STING-A-WAY"**...."will stop pain and itch of contact with most poisonous or venomous insect and plants almost immediately.";
>
> **"BEACH-AID"**...."stop jellyfish pain" and "stop sunburn pain".

The labels for the above products also state that they contain as active ingredients, "Process water (steam collected after passing through selected botanicales) and Sodium Hypochlorite."

Because of the claims and intended uses cited, these products are drugs within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act). We do not

have any information which shows that your products, or similarly labeled and formulated OTC drug products, were marketed in the United States prior to December 4, 1975. We do not know of any substantial scientific evidence demonstrating that your products are generally recognized as safe and effective for their intended uses.

Therefore, the above five products are also new drugs [Section 201(p) of the Act] which may not be legally marketed (Section 505 of the Act) because no new drug application pursuant to Section 505(b) is in effect with respect to such drugs. These products are misbranded [Section 502(f)(1) of the Act] in that their labeling fails to bear adequate directions for use.

Additionally, these drugs manufactured and processed by your firm are adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the controls used for the manufacturing, processing, packing, or holding of the products are not in conformance with Current Good Manufacturing Practice Regulations (GMPs), Title 21, Code of Federal Regulations (CFR), Parts 210 and 211. Examples of significant violations are:

1. Failure to have a written finished-product stability program including: sample size, storage conditions, testing methods, testing intervals, and number of batches. (21 CFR 211.166)

2. Failure to have a written program or procedures to test drug components to assure identity, strength, quality, or purity. (21 CFR 211.80)

3. Failure to perform calculation of yield. (21 CFR 211.103)

4. Failure to identify drug products with a lot or control number that permits determination of the history of the manufacture and control of the batch. (21 CFR 211.130)

5. Failure to have written procedures for cleaning and maintenance of equipment. (21 CFR 211.67)

6. Failure to have a written program for calibration of equipment. (21 CFR 211.68)

7. Failure to have written procedures for reprocessing of batches that do not conform to standards or specifications. (21 CFR 211.115)

The above list of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that all your drug products are in compliance with federal law and regulations. Failure to promptly correct these violations and prevent future

violations may result in regulatory action without further notice such as seizure and/or injunction.

Within 15 working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct these violations, including an explanation of each step being taken to prevent the recurrence of the violation. If corrective action cannot be completed within 15 days, state the reason for the delay and the time frame within which the corrections will be completed.

Your reply should be addressed to the Food and Drug Administration at the above address, Attention: Todd W. Cato, Compliance Officer.

Sincerely,

Joseph R. Baca
Dallas District Director

JRB:TWC:jab